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Randolf Von Oepen

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

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3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/523,217	Applicant(s) VON OEPEN ET AL.	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-57, 71, and 72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-57, 71 and 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/7/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 4/26/2007 have been fully considered but they are not persuasive. Applicant argues that the device of Kim does not show a filament disposed through the eyelet of the bar. However, as seen in figs. 24 and 25, the eyelet of the bar has been threaded over the filament (see col. 24 ll. 34-38).
2. Applicant also argues that Kim fails to disclose a bore formed in the bar, a filament disposed through the bore. The examiner incorrectly asserted that the embodiment shown in fig. 3a and 3b includes a bore formed laterally through the bar. Kim does not disclose a bore in this embodiment. However, such a bore (103) is formed in the embodiment shown in fig. 9a and as shown in fig. 24, the bore has a filament threaded through it. The rejections over Kim now reflect that Kim discloses both a bore and an eyelet on the bar shown in fig. 9a, with filament threaded through both the bore and eyelet.
3. Regarding the amendments to claims 36 and 50, the limitation of "the bar is configured to apply an internal compressive force upon a distal lateral surface of a vessel such that a lumen of the vessel is narrowed" is functional language and the prior art apparatus must only be capable of performing such a function to anticipate the claim; the prior art must include all structural limitations but does not need to disclose the apparatus carrying out the function. The prior art of Kim, Kensey, Nash, and Bonutti have all of the claimed structure of 36 and are capable of performing the claimed function if pressed against the distal lateral surface of a vessel.
4. Applicant also argues that the tensioning device taught by Nash is not elastomeric. The examiner indicated in the previous office action that the flexible device of Nash was being considered an equivalent alternative to an elastomeric device since it has the same structure of

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an upright, a plurality of legs, and a grip which comprises a V-shaped groove and was disclosed as being flexible. However, after further consideration, the examiner has changed the rejection to indicate that the use of elastomeric material would have been obvious to one skilled in the art. Although the passage of Nash pointed out by applicant indicates that the device of Nash can be plastically deformed to form louvers 96, it would have been obvious to one skilled in the art to choose a material that allows the groove arranged to receive the filament to be opened slightly so that a filament can be placed within the groove and the groove will close slightly allowing a stronger hold. This can only be achieved if the material is elastic to some degree. Even with an elastomeric material, grips similar to the louvers 96 made of elastomeric material would have been well within the purview of one skilled in the art.

5. New rejections have also been made over Bonutti (RE 36,974).

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 36-40, 44, 45, 47, 50-51, 54-56, and 71** are rejected under 35 U.S.C. 102(b) as being anticipated by Kim (U.S. 5,810,884). Kim discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having a proximal and distal ends and a first bore extending laterally therethrough, and a filament disposed through the first bore (103), wherein the bar is configured to apply a compressive force upon a distal lateral surface of a vessel (fig. 9a and 24). The bore is being

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considered lateral since it extends from one side of the bar to another side of the bar. It is noted that the limitation "configured to apply an internal compressive force upon a distal lateral surface of a vessel such that a lumen of the vessel is narrowed" is functional language and the device must only be capable of carrying out the function. The device of Kim has all of the claimed structure and is capable of applying this force if it is implanted in a configuration such that it pushes against the outer surface of the lower wall of the vessel.

8. Regarding claim 50, Kim further discloses an eyelet (104) with the filament disposed through it (see fig. 24, 25; col. 24, ll. 29-39).

9. Regarding claims 37 and 54, the apparatus further includes a delivery sheath having a proximal and distal end, a lumen therebetween and a sharpened tip at the distal end. The lumen is configured to contain the filament and bar (see fig. 10-13).

10. Regarding claims 38 and 55, the apparatus includes a push rod disposed in the lumen of the delivery sheath proximal bar (270).

11. Regarding claim 39, the bar is rectangular in shape.

12. Regarding claims 40 and 56, the rod (buttressing support member) may be biodegradable (col. 13, ll. 29-33).

13. Regarding claims 45, the bar includes an eyelet (104) and a bore (103), the filament being disposed through both the eyelet and the bore.

14. Regarding claim 47, the eyelet is coupled to the central region and the first bore is disposed in a distal region of the bar (see figs. 9a, 24, 25).

15. Regarding claim 51, the eyelet is in the central region of the bar.

16. Regarding claim 54, the apparatus further includes a delivery sheath having a proximal and distal end, a lumen therebetween and a sharpened tip at the distal end. The lumen is

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configured to contain the filament and bar (that is to say, it is capable of containing the bar with the eyelet).

17. Regarding claim 71, the internal compressive force is functional and the device must only be capable of delivering a compressive force that is sufficient to cause the vessel to narrow and promote coagulation of the blood near the puncture. The device is capable of this; a person can, by hand or by another apparatus, apply enough pressure to the apparatus to deliver such a force.

18. **Claims 36, 39, 40, 44, and 71** are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (Re 36,974). Bonutti discloses an apparatus for facilitating sealing of a puncture formed in a proximal later surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first bore extending laterally therethrough and a filament disposed through the first bore (see fig. 20) wherein the bar is configured to apply an internal compressive force upon a distal lateral surface of a vessel such that a lumen of the vessel is narrowed. It is noted that the limitation "configured to apply an internal compressive force upon a distal lateral surface of a vessel such that a lumen of the vessel is narrowed" is functional language and the device must only be capable of carrying out the function. The device of Bonutti has all of the claimed structure and is capable of applying this force if it is implanted in a configuration such that it pushes against the outer surface of the lower wall of the vessel.

19. Regarding claim 39, the bar is cylindrical.

20. Regarding claim 40, the bar may be biodegradable (see col. 3, ll. 40-41).

21. Regarding claim 44, the bore (188) is being considered disposed in a central region of the bar. The central region is being defined as the region that stretches from an outer edge of bore (190) to the outer edge of bore (188).

22. Regarding claim 71, the internal compressive force is functional and the device must only be capable of delivering a compressive force that is sufficient to cause the vessel to narrow and promote coagulation of the blood near the puncture. The device is capable of this; a person can, by hand or by another apparatus, apply enough pressure to the apparatus to deliver such a force.

23. **Claims 50-51 and 57** are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (U.S. 5,411,520). Nash et al. discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first eyelet to the bar (fig. 12), a filament disposed through the eyelet, wherein the bar is configured to apply a compressive force upon a distal lateral surface of a vessel. It is noted that the limitation "configured to apply an internal compressive force upon a distal lateral surface of a vessel such that a lumen of the vessel is narrowed" is functional language and the device must only be capable of carrying out the function. The device of Nash has all of the claimed structure and is capable of applying this force if it is implanted in a configuration such that it pushes against the outer surface of the lower wall of the vessel.

24. Regarding claim 57, Nash discloses a tensioning device (fig. 13, 14, and 26) configured to hold the filament in a tensioned state.

25. **Claims 36, 44, 48, and 71** are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (U.S. 5,545,178). Kensey et al. disclose an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having a proximal and distal ends and a first bore extending laterally therethrough, and a filament disposed through the first bore, wherein the bar is configured to apply a compressive force upon a distal lateral surface of a vessel (fig. 1 and 8).

26. Regarding claim 44, the first bore is in a central region of the bar.

27. Regarding claim 48, the device further comprises a second bore extending laterally through the bar, wherein the filament is disposed between both the first and the second bore.

28. Regarding claim 71, the internal compressive force is functional and the device must only be capable of delivering a compressive force that is sufficient to cause the vessel to narrow and promote coagulation of the blood near the puncture. The device is capable of this; a person can, by hand or by another apparatus, apply enough pressure to the apparatus to deliver such a force.

***Claim Rejections - 35 USC § 103***

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. **Claims 46, 52, and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim.

31. Regarding claim 46, Kim discloses the invention substantially as stated above including the use of both a bore and an eyelet on a bar with a filament disposed through the bore and eyelet. Kim fails to disclose that the eyelet is coupled to the distal region and the bore is coupled to the central region and instead discloses the bore at the distal region and the eyelet in the central region. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to switch the location of the eyelet with the location of the bore since it has been held that rearranging parts of an invention involves only routine skill in the art (*In re Japikse*, 86 USPQ 70).



32. Regarding claims 52 and 53, Kim discloses the invention substantially as stated above including the use of two attachment points, a bore and an eyelet to attach the filament to the bar; the eyelet is in the central region and the bore is in the distal region. Kim fails to disclose the use of a second eyelet attached to the bar at the distal region and instead discloses a bore at this position. At the time of the invention, it would have been obvious to one skilled in the art to modify the device of Kim to use a second eyelet instead of a bore (103) because Applicant has failed to disclose that the use of two eyelets instead of an eyelet and a bore provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art would have expected the device of Kim and applicant's invention to work equally well with the claimed two eyelets or an eyelet and a bore as taught by Kim. Therefore, it would have been an obvious to one skilled in the art to modify the device of Kim to use an eyelet instead of a bore for the distal attachment point since such a modification is considered a mere design choice which fails to patentably distinguish the claimed invention from the prior art of Kim.

33. **Claims 41-43, 57, and 72** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Nash et al. Kim discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned stated.

34. However, Nash et al. discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash et al. discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the

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grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device. Although the material can be plastically deformed, it would have been obvious to one skilled in the art to use an elastomeric material since one skilled in the art would have recognized the advantage of having a groove that, in its closed state, is thinner than the diameter of the filament in order to have a stronger grip on the filament. In order to place the filament in such a groove, a material such as an elastomeric material that can be deformed but returns back to its original configuration, would have been an obvious material choice to one skilled in the art. It would have been within the purview of one skilled in the art to be able to form grips similar to the louvers with an elastomeric material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Kim to include a tensioning device as made obvious by Nash et al. in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

35. Regarding claim 72, the narrowing of the vessel is functional language/intended use and the device must only be capable of delivering a compressive force that is sufficient to cause the vessel to narrow and promote coagulation of the blood near the puncture. The device is capable of this; a person can, by hand or by another apparatus, apply enough pressure to the apparatus to deliver such a force.

36. **Claims 41-43 and 72** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Nash et al. Bonutti discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned state.

37. However, Nash et al. discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash et al. discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown

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in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device, which is being considered an equivalent alternative to an elastomeric material. Although the material can be plastically deformed, it would have been obvious to one skilled in the art to use an elastomeric material since one skilled in the art would have recognized the advantage of having a groove that, in its closed state with no filament therein, is thinner than the diameter of the filament in order to have a stronger grip on the filament. In order to place the filament in such a groove, a material such as an elastomeric material that can be deformed but returns back to its original configuration would have been an obvious material choice to one skilled in the art. It would have been within the purview of one skilled in the art to be able to form grips similar to the louvers with an elastomeric material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Bonutti to include a tensioning device as made obvious by Nash et al. in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

38. Regarding claim 72, the narrowing of the vessel is functional language/intended use and the device must only be capable of delivering a compressive force that is sufficient to cause the vessel to narrow and promote coagulation of the blood near the puncture. The device is capable of this; a person can, by hand or by another apparatus, apply enough pressure to the apparatus to deliver such a force.

39. **Claims 45-47** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Rollero et al. (US 6,506,197). Bonutti discloses the invention substantially as stated

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above including the use of either a bore or an eyelet through which a filament is threaded.

Bonutti fails to disclose the use of a bore and an eyelet on the same bar.

40. However, Rollero et al. discloses that it is old and well known in the art to include a plurality of holes in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Bonutti. Therefore, it would be obvious to one of ordinary skill in the art to employ three holes or three eyelets as made obvious by Rollero et al. in the device of Bonutti so that suture can be securely attached to the bar if desired. This modified device does not include both an eyelet and bore, with one being in the center and one being in the distal region.

41. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use an eyelet and a bore, one being in the center and one being in the distal region because applicant has not disclosed that either of these configurations provides an advantage, is used for a particular purpose, or solves a stated problem over the use of either two bores, one in the central region and one in the distal region of the bar, or two eyelets, one in the central region and one in the distal region. One of ordinary skill in the art, furthermore, would have expected modified Bonutti's device, and applicant's invention, to perform equally well with either two bores or two eyelets, one in the central region and one in the distal region, or the claimed one eyelet and one bore, one in the central region and one in the distal region because both would perform the same function of providing a means of attaching the bar to the filament.

42. Therefore, it would have been prima facie obvious to modify Bonutti to obtain the invention specified in claims 45-47 because such a modification would have been considered a

mere design consideration which fails to patentably distinguish over the prior art of modified Bonutti.

43. **Claim 49** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. in view of Rollero et al. (U.S. 6,506,197). Kensey et al. disclose the invention substantially as stated above including a bar that has a first and second bore. The bores disclosed by Kensey et al. are both in a central region of the bar.

44. However, Rollero et al. discloses that it is old and well known in the art to use suture bars that include 3 holes as seen in Fig. 6a. wherein suture is threaded through each bore (see fig. 6a). Rollero et al. disclose that the three holes provide a way to tie suture to the bar such that the suture bar cannot move along the suture. Incorporating the three hole design in fig. 6a onto the bar of Kensey et al. would allow the bar to be firmly attached to the suture so that it cannot become displaced along the suture during its insertion. Using this configuration, there is a first bore in the central region of the bar and a second bore in the distal region of the bar through which the filament is disposed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Kensey et al. to include three holes as made obvious by Rollero et al. in order to gain the advantage of being able to thread the filament through either two of the holes in a pulley configuration or through three holes such that the bar can be firmly attached to the suture.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 10/25/2007

  
GLENN K. DAWSON  
PRIMARY EXAMINER